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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,590	09/02/2004	Eva Trofast	06275-415US1	1412

26164 7590 10/17/2007
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EXAMINER	
EBERHARD, JEFFREY S	

ART UNIT	PAPER NUMBER
4133	

MAIL DATE	DELIVERY MODE
10/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,590	TROFAST ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Eberhard, Ph.D.	4133	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/2/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The use of the trademark Symbicort® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

3. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred

modification or alternative. The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrases "has not spherical shape" recited in claim 2, and "giving an iso-osmotic solution to saline" recited in claim 8 are awkward, as is the entirety of claim 6. All appear to be literal translations from a foreign language into English, and each must be restated clearly. Claim 7 too should be rewritten using commas rather than semi-colons to delimit the members of the list.

Claims 3 and 4 recite the limitations on the size of the "coarse particles may have" in the formulation of claim 1. There is insufficient antecedent basis for this limitation in the claim, and the phrase "may have" is *prima facie* indefinite.

Claims 5 and 6 recite Markush groups improperly, thus rendering them indefinite. They use the presumptively open-ended transition phrases "for example," and "e.g." rather than the proper closed transition phrase "the group consisting of." See *Gillette Co. v. Energizer Holdings Inc.*, 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005).

Claim 8 recites "A method of selecting a crystalline excipient" in the opening statement, then goes on to specify the result of that selection in section i), thus rendering the claim indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Baichwal (US 5,738,865).

The instant claims recite a pharmaceutical formulation for respiratory administration comprising a drug and maltitol excipient. Applicant further recites that the particle size of the formulation is from 20 to 800 μm, and the active pharmaceutical ingredient is chosen from among certain β-2 adrenoceptor agonists, anticholinergic bronchodilators, glucocorticosteroids or anti-allergy medicaments.

Baichwal teaches a "Controlled release powder insufflation formulation" (Abstract), with "an average particle size of from about 45 to 355 microns" (column 5, lines 38-40). The formulation comprises a maltitol excipient (column 7, lines 43-49) and drugs such as the glucocorticosteroid budesonide (column 10, line 21) or the β-2 adrenoceptor agonist terbutaline (column 10, line 32).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baichwal in view of Edwards (US 5,985,309).

Baichwal is discussed above, but it does not teach particles with non-spherical shape, formulations comprising multiple active pharmaceutical ingredients, and certain specific properties of an excipient recited by Applicant in claim 8.

Edwards teaches excipient selection in formulations comprising inhaled therapeutic agents (column 6, line 63, *et seq.*). Specifically, Edwards teaches non-spherical excipients that are especially useful altering the rate of release of therapeutic agents from inhaled particles (column 9, lines 17-29). Thus, a person of ordinary skill in the art at the time the invention was made would have been motivated to use non-spherical particles to optimize availability of specific inhaled therapeutic agents. It would have also been obvious to a person of ordinary skill in the art at the time the invention was made to have selected the corn derived sugar maltitol as a plant based non-ionic excipient because of its widespread use in the art as such, and per claim 8 of the instant application, maltitol is a humectant (hygroscopic) and non-reducing. Edwards also teaches use of a polysaccharide excipient such as maltitol at a level of at least 5.5% (10-50%, column 8, lines 36 and 37). See the FCC Maltitol Monograph, page 1, Description/Function and Requirements/Reducing Sugars, respectively). Given the molecular weight and equivalent ratios

of maltitol/saline (344/57 and ½, respectively), it is well within the purview of one of ordinary skill in the art to formulate a solution iso-osmotic in maltitol and sodium chloride.

Both Baichwal and Edwards teach numerous individual embodiments each comprising a different drug. Thus it would have been obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated multiple drugs in a single formulation of inhaled therapeutic agents where use of multiple medicaments are indicated. Baichwal teaches that both budesonide and fluticasone (column 10, lines 10-35) are used for the claimed process, and using them together would only enhance their desired therapeutic effect.

Application Status and Examiner Contact Information

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Eberhard, Ph.D. whose telephone number is (571) 270-3289. The examiner can normally be reached on 7:30 am to 4:00 pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jeffrey S. Eberhard, Ph.D.
Patent Examiner

JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER